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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/735,056

12/11/2000

Leonard Katz

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4609

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12/16/2004

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EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/735,056	<b>Applicant(s)</b> KATZ ET AL.	
	<b>Examiner</b> William W. Moore	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 59,61,72-75,77-81 and 84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59,61,72-75,77-81 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment and Terminal Disclaimer*

Applicant's Terminal Disclaimer filed September 27, 2004, is proper and removes the basis for the rejection of record of claims herein under the judicially-created doctrine of obviousness-type double patenting. The claim amendments and cancellations made in the Response filed September 27, 2004, remove the bases for objections of record of the claims herein and several of the bases for rejections of record of claims under the first and second paragraph 35 U.S.C. § 112, but others remain. Claims 59, 61, 72-75, 77-81 and 94 are pending in the application.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59, 61, 77, 78 and 84 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the communication mailed May 25, 2004.

Applicant's arguments in the Response filed September 27, 2004, have been fully considered but they are not persuasive. Applicant indicates a belief at page 10 therein that the rejection of record was stated under the second paragraph of the statute but it was instead stated under the first paragraph of the statute in the communication mailed May 25, 2004. This is essentially the rejection of record applied to claim 84 introduced in the Response filed February 9, 2004, and affecting claims 59, 61, 77 and 78. It is noted that claim 84 was proposed in the communication mailed June 2, 2003, in order to advance prosecution because it resolved several aspects of rejections stated under

the second paragraph of the statute in that communication. Applicant's arguments at pages 10 and 11 of Response suggest that the basis for an adequate written description of the method disclosed in the specification is embodied in the term in the preamble of claim 84, "polyketide-producing microorganism", but a method of claim 84 must include methods of claims, such as claims 77 and 78, that depend therefrom. It is agreed that the specification provides an adequate description of methods wherein a Class 1 polyketide synthase [PKS] gene is selection from a macrolide producing microorganism of claim 77, and from a microorganism of the *Actinomycetales* family that comprises the genera recited in claim 72. But Applicant's series of specifications make no distinction between Class 1 and Class 2 PKS genes and a limitation Applicant argues discussed in the specification is absent from claim 84. Applicant does not independently argue that the specification provides an adequate written description of the practice of a claimed method where "polyketide-producing microorganisms" are the source of PKS genes producing classes of polyketides absent from claim 77. Neither does Applicant argue that the specification provides an adequate written description of practice of a claimed method where a polyketide-producing microorganism is a sources of PKS genes producing "derivatives and analogs" of recognized macrolide, polyether, tetracycline, polyene, and ansamycin classes, or of the macrolide class of claim 78. Indeed, the specification does not define further kinds of polyketides that are "derivatives and analogs" of these art-recognized classes. This rejection may be overcome by canceling claim 77 and incorporating the limitation macrolide in the preamble of claim 84 or by a showing that the specification somewhere provides support for reciting in the preamble of claim 84 some greater, but definite, term, such as a Class 1 polyketide synthase, as well as any further embodiments adequately described in the specification.

Claims 59, 61, 77, 78 and 84 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification is not enabling for any embodiment of a directed

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biosynthesis of any and all "specific polyketide analog[s]" by isolation and manipulation of generic polyketide synthase-encoding genes wherein a  $\beta$ -carbonyl processing domain-encoding region is inactivated or added in any gene associated with polyketide biosynthesis in any conceivable microorganism identified as producing a polyketide for the reasons set forth in the communication mailed May 25, 2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Applicant's arguments filed September 27, 2004, have been fully considered but they are not persuasive. Applicant suggests at page 10 therein that the rejection of record was stated under the second paragraph of the statute but it was instead stated under the first paragraph of the statute in the communication mailed May 25, 2004. This is essentially the rejection of record applied to claim 84 introduced in the Response filed February 9, 2004, affecting claims 59, 61, 77 and 78. The communication mailed June 2, 2003, had proposed claim 84 to advance prosecution by resolving several aspects of rejections stated under the second paragraph of the statute in that communication. Applicant's arguments addressing the factors discussed in the decision of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), at pages 11 and 12 of Response assert that no undue experimentation would be required to practice a claimed method so long as it involved manipulations of clause (3) of claim 84, or of claims 59 and 61. Applicant does not, however, suggest that the teachings of the specification enable the use of manipulations of clause (3) of claim 84, or of claims 59 and 61 with undisclosed of PKS genes producing "derivatives and analogs" of recognized macrolides to practice a method of preparing further derivatives or analogs of the undisclosed derivatives and analogs contemplated in the preamble of claim 84 in view of its embrace of claim 77 depending therefrom. This rejection may be overcome by canceling claim 77 and incorporating the limitation macrolide in the preamble of claim 84.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59, 61, 72-75, 77-79 and 84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the communication mailed May 25, 2004.

Applicant's arguments filed September 27, 2004, have been fully considered but they are not persuasive because they do not address two remaining issues among the rejections of record. Claim 84 remains indefinite in reciting, in its preamble, "specific polyketide analog[s]" because a method of claim 84 provides no result that agrees with the preamble where process steps are too general to indicate the production of particular polyketide analogs that are "specific". Claims 80 and 81 are not included in this aspect of the rejection, but claims 59, 61, 72-75, and 77-79 are included in this aspect of the rejection where they depend from claim 84 but cannot resolve the indefinite description of its preamble. Amending the claim to replace the term "specific polyketide analogs" with the term "modified polyketide" would overcome this aspect of the rejection.

Claim 77 remains indefinite in reciting "derivatives or analogs thereof" because this indicates Applicant intends to describe a polyketide that is a "derivative or analog" of a "specific polyketide analog" of claim 84 from which it depends, but claim 77 cannot logically be drawn to a derivative or analog of any of the preceding genera of polyketides where claim 84 already requires that a claimed method result in a "specific polyketide analog". Claims 78-81 are included where they depend from claim 77 but do not resolve its indefinite description. Claim 81 remains indefinite in failing to further limit the scope of claim 84 from which it depends in reciting "protein" where Applicant intends, the disclosure requires, and claim 84 provides antecedent basis only for a particular protein, a polyketide synthase.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore  
December 10, 2004

  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE  
WASHINGTON, D.C. 20535